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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,091	02/23/2000	RICHARD ANDREW KAY	350013-66	7544

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EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

100

**Office Action Summary****Application No.**

09/424,091

**Applicant(s)**

KAY, RICHARD ANDREW

**Examiner**

Maher M. Haddad

**Art Unit**

1644

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/25/01 and 04 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.
2. Applicant's election of claims 1-11 and 18-20 of the embodiment of the method of identifying an antigen-responsive T cell wherein the method comprises a method which quantitates the amount of specific T cell receptor RNA or the amount of T cell receptor RNA in a specific subset, as recited in claims 2-11, filed 6/25/01, is acknowledged. Upon reconsideration, however, the previous restriction requirement is vacated. A new restriction follows. The Examiner apologizes for any inconvenience or delay.
3. The Examiner considers claims 12-14 improperly depends on claims 2-11 because after reviewing the specification, it does not appear that the recited antibodies were used in conjunction with the PCR gene expression. The restriction has therefore been set forth for the methods encompassing the recited antibodies as Groups independent from PCR methods recited in claims 2-11.
4. Restriction is required under 35 U.S.C. 121 and 372.  
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.
  - I. Claims 2-6, 10-11 and 15-17, drawn to a method of identifying an antigen-responsive T cell within a population of T cells using PCR, wherein each T cell receptor comprises a specific V $\beta$  region.
  - II. Claims 2-5, 7, 10-11 and 15-17, drawn to a method of identifying an antigen-responsive T cell within a population of T cells using PCR, wherein each T cell receptor comprises a specific V $\alpha$  region.
  - III. Claims 2-5, 8, 10-11 and 15-17, drawn to a method of identifying an antigen-responsive T cell within a population of T cells using PCR, wherein each T cell receptor comprises a specific V $\beta$  region and a specific V $\alpha$  region.
  - IV. Claims 2-5, 9, 10-11 and 15-17, drawn to a method of identifying an antigen-responsive T cell within a population of T cells using PCR, wherein each T cell receptor comprises a specific J region.

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- V. Claims 6, 8 and 12-13, drawn to a method of identifying an antigen-responsive T cell within a population of T cells using antibodies, wherein the antibody is an anti-specific V $\beta$  region.
- VI. Claims 7-8, 12 and 14, drawn to a method of identifying an antigen-responsive T cell within a population of T cells using antibodies, wherein each T cell receptor comprises an anti-specific V $\alpha$  region.
- VII. Claims 18-20, drawn to a method of treating a patient with an antigen-mediated disease with T cell vaccination.
- VIII. Claims 18-20, drawn to a method of treating a patient with an antigen-mediated disease with anti-TCR antibody treatment.
- IX. Claims 18-20, drawn to a method of treating a patient with an antigen-mediated disease with peptide immunization.

Claim 1 is a linking claim and will be examined along with any one of Groups I-VI.

5. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of claim 1 was found to have no special technical feature that defined the contribution over the prior art of Wigzell et al (WO-A-94 14067, IDS) (see entire document).

Wigzell teaches a method of identifying the V gene usage of T cells which are responsive in sarcoidosis patients. The method comprises obtaining bronchoalveolar samples from sarcoidosis patients (i.e. samples containing T cells which have responded to antigen) and samples from healthy subjects, and incubating the T cells with TCR specific monoclonal antibodies (with specificity for specific V $\alpha$  or V $\beta$  regions) and comparing the V gene usage of T cells in sick and healthy subjects (see entire article, including pages 47-62).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.


6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.  
Patent Examiner  
Technology Center 1600  
February 20, 2004

  
CHRISTINA CHAN  
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